

## REMARKS

Per instruction of the Examiner, Applicant elects Species I as required by the Election/Restriction requirement. Claims 4-14 and 16-21 are considered by the Applicant to apply to Species I. However, as seen in Figures 16A, 16B, 16C and 23, the scalpel of the instant invention clearly provides selective control of both depth and width of incision in the same scalpel.

The scalpel, as claimed in currently pending Claim 4, clearly cites selectively varying both depth and width of incision. For this reason, it is requested that consideration be given to removing the restriction of Claim 15, which is currently, by instruction, withdrawn.

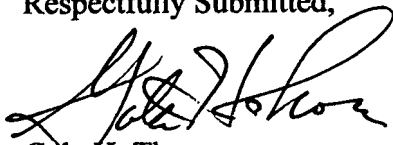
Independent of cancellation or non-cancellation of Claim 15, there is no change in inventorship.

A complete listing of text of all claims, including status of the claims, is enclosed herewith.

## CONCLUSIONS

Claim 4 has been amended. Claims 15 and 30-37 have been withdrawn. However, it is respectfully submitted that Claim 15 is not patentably distinct and is a variant of the scalpel claimed in Claim 4.

Respectfully Submitted,



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## **The Claims**

1. (Withdrawn) A planar, split scalpel blade element for producing an incision having a predetermined width and a predetermined, substantially constant, predetermined depth, said blade element comprising:

two juxtaposed elongated components aligned in a first plane with each component split away from the other component along a medial second plane which is orthogonal to the first plane, when medially aligned, said components jointly forming a distally disposed piercing end and comprising a common hinged joint aligned with the second plane at a proximal end;

a first component of the two components comprising a first knife blade at the piercing end, which is sharpened to be effective as a piercing and transverse cutting tool, and an inwardly disposed elongated first edge which is angularly displaced relative to the second plane to thereby provide a guide by which the piercing end of the component is skewed away from the second plane as a part of an actuator is displaced there along in a direction substantially parallel to the second plane toward the piercing end;

a second component of the two components comprising a second knife blade at the piercing end, which is sharpened to be effective as a piercing and transverse cutting tool,

and an inwardly disposed elongated second edge which is angularly displaced relative to the second plane to thereby provide a guide by which the piercing end of the component is skewed away from the second plane as a part of an actuator is displaced there along in a direction substantially parallel to the second plane toward the piercing end;

the first and second component each comprising a third and fourth edge, respectively, each third and fourth edge being respectively disposed transversely outward from said first edge and second edge, each third and fourth edge comprising an elongated substantially straight length which is substantially parallel to the second plane when the components are juxtaposed and aligned with the second plane to thereby provide a pair of guides which interact with associated side stops which are fixed relative to blade movement and which obstruct sideways displacement of the first and second components thereby causing each actuator part and blade component to move distally as a unit without outward skewing of the first and second components until the blade element is distally displaced to the predetermined depth;

said first component further comprising a first wing defined by a first distal edge outwardly disposed between a

proximal segment of said first knife blade and the distal end of the straight length of the third edge, said first wing further comprising a first arcuate, concave edge which is joined to a proximal end of the third edge, the first distal edge providing an interface against an associated distal stop which limits forward displacement of the first component whereat the first concave edge is disposed to provide relief from the associated side stop of the third edge to thereby permit outward skewing of the first component as the actuator part continues to be distally displaced and thereby skew the first knife blade outward, away from the second plane, to widen the incision to the portion of the predetermined width formed by the first component of the blade; and

said second component further comprising a second wing defined by a second distal edge outwardly disposed between a proximal segment of said second knife blade and the distal end of the straight length of the fourth edge, said second wing further comprising a second arcuate, concave edge which is joined to a proximal end of the fourth edge, the second distal edge providing an interface against an associated distal stop which limits forward displacement of the second component whereat the second concave edge is disposed to provide relief from the associated side stop of the fourth

edge to thereby permit outward skewing of the second component as the actuator part continues to be distally displaced and thereby skew the second knife blade outwardly away from the first knife blade to widen the incision to the portion of the predetermined width formed by the second component of the blade.

2. (Withdrawn) A planar, split scalpel blade element according to Claim 1 wherein the first transverse distal edge comprises a curvature which acts to maintain a constant depth of penetration of the proximal end of the scalpel blade as the first component is transversely displaced against the associated distal displacement limiting stop.

3. (Withdrawn) A planar, split scalpel blade element according to Claim 1 wherein the second transverse distal edge comprises a curvature which acts to maintain a constant depth of penetration of the proximal end of the scalpel blade as the second component is transversely displaced against the associated distal displacement limiting stop.

4. (Once amended) A wire steered scalpel for selectively variably enlarging catheter entry site, in both width and depth dimensions, the entry site having a guide wire inserted thereat preparatory to introducing a catheter, said scalpel comprising:

a housing comprising a pathway having an entry portal and an exit portal through which the guide wire is threadably disposed to facilitate steering the housing to the entry site, the entry portal being proximal to the entry site when the scalpel is used;

a split scalpel blade having a pair of sharpened points, said blade being within the housing and aligned with the pathway to lance, at the entry site, to be extended from the housing and thereby produce an incision having a predetermined width and depth; and

an actuator comprising a plurality of blade interfacing parts by which the scalpel blade is manually displaced relative to the housing and pathway to cause the blade to lance.

5. (Original) A wire steered scalpel according to Claim 4 wherein the scalpel blade is medially split to comprise two scalpel components aligned to provide a distally disposed piercing end and a proximally disposed end whereat the two components comprise a common hinge connection.

6. (Original) A wire steered scalpel according to Claim 5 wherein the housing comprises stops and the blade comprises guide edges which interface to the actuator parts and side stops to maintain the scalpel components aligned until the scalpel pierces the entry site to the predetermined depth.

7. (Original) A wire steered scalpel according to Claim 4 wherein the housing comprises at least one stop for limiting travel of the scalpel blade components, thereby limiting depth of the lance and ending a first lancing motion of the scalpel.

8. (Original) A wire steered scalpel according to Claim 4 wherein the guide edges of the blade comprise relief for the side stops when the scalpel blade reaches the at least one blade travel limiting stop, thereby permitting the components to be displaced transversely relative to direction of displacement of the actuator, thereby widening the incision as a second motion of the scalpel blade.

9. (Original) A wire steered scalpel according to Claim 4 wherein the blade comprises at least one distally disposed wing which comprises an edge which interfaces with the at least one stop, the interfacing edge having a curvature which substantially maintains a constant depth of incision as each blade component is transversely displaced.

10. (Original) A wire steered scalpel according to Claim 4 wherein said housing in cooperation with said actuator define selectable stops whereby actuator travel is limited and, as a result, transverse displacement of the components is limited to selectively control and limit width of an incision.

11. (Original) A wire steered scalpel according to Claim 4 wherein said housing comprises a top part and a bottom part.

12. (Original) A wire steered scalpel according to Claim 11 wherein said top and bottom parts are molded as a single unit wherein said parts comprise a common living hinge which permits the parts to close together as a clam shell.



13. (Original) A wire steered scalpel according to Claim 12 wherein said scalpel blade comprises a medially depressed channel into which a guide wire is displaced preparatory to closing the top and bottom parts together.

14. (Original) A wire steered scalpel according to Claim 12 wherein said actuator parts comprise latches which act against the scalpel blade to secure the blade to a part of the housing while the housing is open.

15. (Withdrawn) A wire steered scalpel according to Claim 4 wherein said housing comprises an adjustable distally disposed nose part comprising a distal face which is adjustable along a longitudinal medial line to selectably limit scalpel blade displacement distally beyond the distal face and thereby limit depth of penetration of the blade.

16. (Original) A wire steered scalpel according to Claim 4 wherein said housing comprises an enclosed pathway for a guide wire threaded there through, said pathway having a distal opening and a proximal opening whereby the scalpel is displaced along the guide wire to an incision site.

17. (Original) A wire steered scalpel according to Claim 16 wherein said housing comprises a pathway offset to provide a point of coincidence between the guide wire and the sharpened point of a fully extended scalpel blade.

18. (Original) A wire steered scalpel according to Claim 4 wherein said actuator comprises a plurality of hingeably interconnected parts, including a manual interface component, which cooperate to provide a mechanical advantage whereby linear displacement of the scalpel blade is greater than manual displacement of the interface component.

19. (Original) A wire steered scalpel according to Claim 18 wherein said actuator parts are molded as a single part comprising living hinges therewith molded.

20. (Original) A wire steered scalpel according to Claim 18 wherein said actuator comprises a living hinge connection produced by integrally molding at least one housing part with the actuator.

21. (Original) A wire steered scalpel according to Claim 18 further comprising a spring affixed on a first end to the housing and to actuator on a second whereby the blade is automatically returned into the housing after use as a safety feature.

22. (Withdrawn) A method for making a carefully controlled incision at an entry site comprising the steps of:

(a) providing a guide-wire steered scalpel, said scalpel comprising:

a housing comprising a pathway having an entry portal and an exit portal through which a guide-wire is threadably disposed to facilitate steering the housing to the entry site, the entry portal adjoining the entry site when the scalpel is used;

a split scalpel blade, having two sharpened blades and associated points, which is disposed within the housing and aligned with the pathway to lance at the entry site, said blade being extended from the housing to thereby produce an incision having a predetermined width and depth; and

an actuator comprising at least one blade interfacing part by which the scalpel blade is manually displaced relative to the housing and pathway to cause

the blade to lance;

(b) displacing a guide-wire which has been previously inserted into an entry site through the entry and exit portals, respectively;

(c) displacing the housing along the guide-wire to the entry site; and

(d) actuating the scalpel blade to pierce the entry site to a predetermined depth and to a predetermined width.

23. (Withdrawn) A method according to Claim 22 wherein step d comprises two separate steps as follows:

(e) extending the scalpel blade from the housing to produce an incision to the predetermined depth; and

(f) a second mode whereby the scalpel blade is split apart to widen the incision to a predetermined width.

24. (Withdrawn) A method according to Claim 23 wherein transition from the first mode to the second mode is continuous and subliminal to a user actuating the scalpel.

25. (Withdrawn) A method according to Claim 22 comprising a further step of retracting the scalpel blade into the housing at the end of the actuating step.

26. (Withdrawn) A method according to Claim 25 wherein the actuating step comprises a step which stores energy in an elastic memory device.

27. (Withdrawn) A method according to Claim 26 comprising an additional step of automatically retracting the scalpel blade into the housing due to release of energy stored in the elastic memory device at the end of the actuating step.

28. (Withdrawn) A method according to Claim 25 wherein the scalpel blade retracting step comprises the following steps:

(g) returning the two scalpel blades to an original juxtaposed state; and

(h) retracting the entire scalpel blade into the housing.

29. (Withdrawn) A method according to Claim 28 wherein step h occurs following completion of step g.

30. (Withdrawn) A method for making a carefully controlled incision at a catheter entry site, wherein a guide wire has been inserted preparatory to introducing a catheter, comprising the steps of:

(a) providing a guide-wire steered scalpel, said scalpel comprising:

a housing comprising a pathway having an entry portal and an exit portal through which a guide-wire is threadably disposed to facilitate steering the housing to the entry site, the entry portal adjoining the entry site when the scalpel is used;

a split scalpel blade, having two sharpened blades and associated points, which is disposed within the housing and aligned with the pathway to lance at the entry site, said blade being extended from the housing to thereby produce an incision having a predetermined width and depth; and

an actuator comprising at least one blade interfacing part by which the scalpel blade is manually displaced relative to the housing and pathway to cause the blade to lance;

(b) displacing a guide-wire which has been previously inserted into an entry site through the entry and exit portals, respectively;

(c) displacing the housing along the guide-wire to the entry site; and

(d) actuating the scalpel blade to pierce the entry site to a predetermined depth and to a predetermined width.

31. (Withdrawn) A method according to Claim 30 wherein step d comprises two separate steps as follows:

(e) extending the scalpel blade from the housing to produce an incision to the predetermined depth; and

(f) a second mode whereby the scalpel blade is split apart to widen the incision to a predetermined width.

32. (Withdrawn) A method according to Claim 31 wherein transition from the first mode to the second mode is continuous and subliminal to a user actuating the scalpel.

33. (Withdrawn) A method according to Claim 30 comprising a further step of retracting the scalpel blade into the housing at the end of the actuating step.

34. (Withdrawn) A method according to Claim 33 wherein the actuating step comprises a step which stores energy in an elastic memory device.

35. (Withdrawn) A method according to Claim 34 comprising an additional step of automatically retracting the scalpel blade into the housing due to release of energy stored in the elastic memory device at the end of the actuating step.

36. (Withdrawn) A method according to Claim 33 wherein the scalpel blade retracting step comprises the following steps:

(g) returning the two scalpel blades to an original juxtaposed state; and

(h) retracting the entire scalpel blade into the housing.

37. (Withdrawn) A method according to Claim 36 wherein step h occurs following completion of step g.